K093983 (pg 1/2)

BIOMET TRAUMA

MAR 19 2010

510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR § 807.93

Submitter: Biomet Trauma
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Establishment Registration Number: 2242816

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Date Prepared: December 22, 2009

Trade/Proprietary Name: SMPle™ Pediatric Submuscular Plating System

Common/Usual Name: Plates/Screws

Classification Name: Single/multiple metallic bone fixation appliances and accessories (21 CFR 888.3030)

Device Panel/Product Code: Orthopedics HRS/HWC

Device Description:

Indications for Use:
The SMPle™ Pediatric Submuscular Plating System is intended for adult or pediatric patients as indicated for long bone fracture fixation and fixation of bones that have been surgically prepared (osteotomy) for correction of deformity, malunions, non-union or arthrodesis. Indications for use include internal fixation of the tibia, fibula, femur, humerus, ulna, and radius.

In pediatric femoral applications, the SMPle™ Pediatric Submuscular Plating System is intended for use in the treatment of femoral fractures, malunions or non-unions, femoral osteotomies required for the correction of deformity, and arthrodesis. Indications for buttressing multi-fragmentary distal femoral fractures include: supracondylar, intra-articular and extra-articular condylar, periprosthetic fractures and fractures in normal or osteopenic bone, non-unions and mal-unions, and osteotomies of the femur.

Summary of Technologies:
The technological characteristics of the SMPle™ Pediatric Submuscular Plating System are the same, or similar to, other legally marketed predicate devices.

This plating system may be placed via a standard open surgical technique or via a sub-muscular technique. These plates may be used in conjunction with other devices and treatment modalities for deformity correction at the discretion of the treating physician.

Substantial Equivalence:
The SMPle™ Pediatric Submuscular Plating System is substantially equivalent to its predicate devices with respect to intended use and indications, technological characteristics, and principles of operation and does not present any new issues of safety or effectiveness. Examples of predicates include: Synthes 3.5 and 4.5 Locking Compression Plates for expanded indications (K082807); Orthopediatrics PediLoc™ Plating Systems (K083286) and the Biomet IQL Plating System (K020221), and the Biomet OptiLock® Periarticular Plating System (K061098). Based upon the engineering analysis and the other information presented in this premarket notification, the SMPle™ Pediatric Submuscular Plating System is equivalent for its intended use to other legally marketed plate and screw systems.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

Biomet Trauma (aka EBI, LP)
% Ms. Margaret Crowe
Regulatory Affairs Project Manager
100 Interpace Parkway
Parsippany, NJ 070654

MAR 19 2010

Re: K093983
Trade/Device Name: SMPle™ Pediatric Submuscular Plating System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: HRS, HWC
Dated: December 23, 2009
Received: December 24, 2009

Dear Ms. Crowe:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K093983 (pg 1/1)

Device Name: SMPle™ Pediatric Submuscular Plating System

The SMPle™ Pediatric Submuscular Plating System is intended for adult or pediatric patients as indicated for long bone fracture fixation and fixation of bones that have been surgically prepared (osteotomy) for correction of deformity, malunions, non-union or arthrodesis. Indications for use include internal fixation of the tibia, fibula, femur, humerus, ulna, and radius.

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Prescription Use X (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Temperature

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K093983